**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Proposals relating to Federal Reserve System benefits.
2. Proposed minutes of the Committee on Employee Benefits meetings.
3. Any items carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: March 18, 1997.

William W. Wiles,

*Secretary of the Board.*

[FR Doc. 97-7189 Filed 3-18-97; 11:35 am]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Universal Newborn Hearing Ad Hoc Group; Teleconference Meetings

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meetings.

*Name:* Teleconference meetings of the Ad Hoc Group for Universal Newborn Hearing Screening (UNHS).

*Times and Dates:* 2 p.m.-3 p.m., April 1, 1997; 2 p.m.-3 p.m., May 6, 1997; 2 p.m.-3 p.m., June 3, 1997; 2 p.m.-3 p.m., July 1, 1997; 2 p.m.-3 p.m., August 5, 1997; 2 p.m.-3 p.m., September 2, 1997.

*Place:* National Center for Environmental Health, Division of Birth Defects and Developmental Disabilities (DBDDD), Room 2103A, Building 101, 4770 Buford Highway, NE, Atlanta, Georgia 30341. Telephone 770/488-7400.

*Status:* Open for participation by anyone with an interest in UNHS. All participants in the monthly conference calls are, by definition, members of the Ad Hoc Group for Universal Newborn Hearing Screening. Persons wishing to participate must E-mail or fax their request 1 week prior to the scheduled teleconference date. The e-mail address is unhs@cdc.gov; the fax number is 770/488-7361. Participants will be notified of the toll-free teleconference phone number and a caller code. Each participant will have the responsibility to call in to connect to the conference call. The conference bridge number is limited to 238 callers.

*Purpose:* This meeting will provide a forum for persons associated with UNHS programs to report and review relevant activities. Each conference call will be comprised of a series of scheduled presentations. Each presentation will be followed by a brief question and answer period. The agenda for the conference call will be determined by the Division of Birth Defects and Developmental Disabilities in collaboration with the Office of Disability and Health, NCEH, (pending approval); in consultation with the National Institute on Deafness and Communicative Disorders, National Institutes of Health; the Bureau of Maternal and Child Health, Health Resources and Services Administration; Office of Special Education and Rehabilitative Services, Department of Education; and others interested in newborn hearing screening.

Suggestions and feedback are invited by conference call planners. Participants requesting to be on the agenda or wishing to make written comments can send their requests or comments to the E-mail address or fax number noted above.

*Matters Discussed:* Topics to be discussed during the meetings include progress on State and National activities to implement UNHS; progress on establishing State and National data systems on UNHS; and guidelines for establishing screening, diagnosis, and intervention protocols.

*For further information contact:* June Holstrum, DBDDD, NCEH, CDC, 4770 Buford Highway, NE, M/S F-15, Atlanta, Georgia 30341, telephone 770/488-7401, fax 770/488-7361.

Dated: March 14, 1997.

Carolyn J. Russell,

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97-7016 Filed 3-19-97; 8:45 am]

BILLING CODE 4163-18-P

### Food and Drug Administration

**[Docket No. 96E-0442]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; CEREBYX®

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for CEREBYX® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CEREBYX® (fosphenytoin sodium). CEREBYX® is indicated for short-term parenteral administration when other means of phenytoin administration are unavailable, inappropriate, or deemed less advantageous. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CEREBYX® (U.S. Patent No. 4,260,769) from Warner-Lambert Co. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CEREBYX® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for

CEREBYX® is 3,748 days. Of this time, 3,218 days occurred during the testing phase of the regulatory review period, while 530 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: May 4, 1986. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on May 4, 1986.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 23, 1995. The applicant claims July 14, 1994, as the date the new drug application (NDA) for CEREBYX® (NDA 20-450) was initially submitted. However, FDA records indicate that NDA 20-450, received by the agency on July 15, 1994, was incomplete. FDA refused this application and notified the applicant of this fact by letter dated September 12, 1994. The completed NDA was then received on February 23, 1995, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: August 5, 1996. FDA has verified the applicant's claim that NDA 20-450 was approved on August 5, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 20, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 22, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 1997.

Stuart L. Nightingale,

*Associate Commissioner for Health Affairs.*

[FR Doc. 97-6976 Filed 3-19-97; 8:45 am]

BILLING CODE 4160-01-F

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**[Docket No. 96E-0440]**

## Determination of Regulatory Review Period for Purposes of Patent Extension; HYCAMTIN™

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for HYCAMTIN™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product HYCAMTIN™ (topotecan hydrochloride). HYCAMTIN™ is indicated for the treatment of patients with metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for HYCAMTIN™ (U.S. Patent No. 5,004,758) from SmithKline Beecham Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 13, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of HYCAMTIN™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for HYCAMTIN™ is 2,644 days. Of this time, 2,485 days occurred during the testing phase of the regulatory review period, while 159 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 4, 1989. The applicant claims January 30, 1989, as the date the investigational new drug application (IND) for HYCAMTIN™ (IND 32,693) became effective. However, FDA records indicate that IND 32,693 was received at FDA on February 2, 1989, and became effective 30 days later on March 4, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section*